of the documented review and material disposition decision;

(3) Any in-process material that has been reprocessed or otherwise reconditioned shall be the subject of a documented review and material disposition decision by an individual qualified by education, training, or experience to determine whether it may be released for use; and

(4) Any rejected in-process material shall be clearly identified as having been rejected for use in infant formula and shall be controlled under a quarantine system designed to prevent its use in infant formula manufacturing or processing operations.

[79 FR 8059, Feb. 10, 2014, as amended at 79 FR 33071, June 10, 2014]

§ 106.55 Controls to prevent adulteration from microorganisms.

(a) A manufacturer of infant formula shall establish a system of process controls covering all stages of processing that is designed to ensure that infant formula does not become adulterated due to the presence of microorganisms in the formula or in the processing environment.

(b) A manufacturer of liquid infant formula shall comply, as appropriate, with the procedures specified in part 113 of this chapter for thermally processed low-acid foods packaged in hermetically sealed containers and part 114 of this chapter for acidified foods.

(c) A manufacturer of powdered infant formula shall test representative samples of each production aggregate of powdered infant formula at the final product stage, before distribution, to ensure that each production aggregate meets the microbiological quality standards in the table in paragraph (e) of this section.

(d) A manufacturer shall make and retain records, in accordance with § 106.100(e)(5)(ii) and (f)(7), on the testing of infant formulas for microorganisms.

(e) A powdered infant formula that contains any microorganism that exceeds the M value listed for that microorganism in the table in paragraph (e) of this section shall be deemed adulterated under sections 402(a)(1), 402(a)(4), and 412(a)(3) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 350a(a)(3)). The Food and Drug Administration will determine compliance with the M values listed below using the latest edition of the *Bacteriological Analytical Manual* (BAM) (*http://www.fda.gov/Food/FoodScienceResearch/LaboratoryMethods/BacteriologicalAnalyticalManualBAM/default.htm*) (accessed April 8, 2013).

Microorganism	n [1]	Sample size	M value
Cronobacter spp.	30	10 g (grams)	[2] 0.
Salmonella spp.	60	25 g	[2] 0.

[1] Number of samples.
[2] None detected.

§ 106.60 Controls to prevent adulteration during packaging and labeling of infant formula.

(a) A manufacturer shall examine packaged and labeled infant formula during finishing operations to ensure that all containers and packages in the production aggregate have the correct label, the correct use-by date, and the correct code established under § 106.80.

(b) Labels shall be designed, printed, and applied so that the labels remain legible and attached during the conditions of processing, storage, handling, distribution, and use.

(c) Packaging used to hold multiple containers of an infant formula product shall be labeled as follows:

(1) Where all containers are the same infant formula product and all bear the same code established under § 106.80, the packaging label shall include the product name, the name of the manufacturer, distributor, or shipper, and the code established under § 106.80.

(2) Where the containers are not the same infant formula product or do not all bear the same code established under § 106.80, the packaging label shall:

(i) Include the product name of each product, the name of the manufacturer,

distributor, or shipper of each product, the code established under §106.80 for each product, and a ''use by'' date that is no later than the ''use by'' date of the container exhibiting the closest ''use by'' date applied to satisfy the requirement of §107.20(c) of this chapter; or

(ii) Include a unique identification number assigned by the packager, provided that the distributor of the package maintains a record linked to such unique number that identifies the product name of each product, the name of the manufacturer, distributor, or shipper of each product, the code established under §106.80 for each product, and the ''use by'' date for each product applied to satisfy the requirement of §107.20(c) of this chapter.

§ 106.70 Controls on the release of finished infant formula.

(a) A manufacturer shall control under a quarantine system designed to prevent use or distribution of each production aggregate of infant formula until it determines that the production aggregate meets all of the manufacturer's specifications, including those adopted to meet the standards of §106.55 on microbiological contamination and of §106.91(a) on quality control procedures, or until the documented review of the failure to meet any of the manufacturer's specifications finds that the failure does not result in, or could not lead to, adulteration of the product.

(b) Any production aggregate of infant formula that fails to meet any of the manufacturer's specifications shall be quarantined under a system designed to prevent its use in the manufacture of infant formula or its distribution until an individual qualified by education, training, or experience has conducted a documented review and has made and documented a material disposition decision to reject the infant formula; to reprocess or otherwise recondition the infant formula; or to approve and release the infant formula. Any production aggregate of infant formula that is reprocessed or otherwise reconditioned shall be the subject of a documented review and material disposition decision by an individual qualified by education, training, or experience to determine whether it may be released for use or distribution.

(c) Any rejected infant formula shall be clearly identified as having been rejected for use and shall be controlled under a quarantine system designed to prevent its release or distribution.

(d) A production aggregate of infant formula, including a reprocessed or reconditioned production aggregate, that does not meet the nutrient requirements of section 412(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 350a(i)) or that has not been manufactured, packaged, labeled, and held under conditions to prevent adulteration under sections 402(a)(1) through (a)(4) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 342(a)(1) through (a)(4)) shall not be approved and released for distribution.

§ 106.80 Traceability.

Each production aggregate of infant formula shall be coded with a sequential number that identifies the product and the establishment where the product was packed and that permits tracing of all stages of manufacture of that production aggregate, including the year, the days of the year, and the period during those days that the product was packed, and the receipt and handling of raw materials used.

§ 106.90 Audits of current good manufacturing practice.

(a) A manufacturer of an infant formula, or an agent of such manufacturer, shall conduct regularly scheduled audits to determine whether the manufacturer has complied with the current good manufacturing practice regulations in this subpart. Such audits shall be conducted at a frequency that is required to ensure compliance with such regulations.

(b) The audits required by paragraph (a) of this section shall be performed by an individual or a team of individuals who, as a result of education, training, or experience, is knowledgeable in all aspects of infant formula production and of the Agency's regulations concerning current good manufacturing practice that such individual or team is responsible for auditing. This individual or team of individuals shall have no direct responsibility for the